JUN 1 4 2001

K011156

SIMS A SMITHS GROUP COMPANY

BCI

Summary of Safety and Effectiveness

Submitter:	SIMS BCI, Inc.
Address:	N7 W22025 Johnson Road Waukesha, WI 53186
Telephone:	(262) 542-3100
Contact:	VP Regulatory Affairs
Prepared:	April 9, 2001
Proprietary Name:	BCI 3403 Sleep Screening Pulse Oximeter
Common/Classification Name:	Pulse Oximeter
Predicate Devices:	BCI 3401 Hand-Held Oximeter (K980714) BCI 3402 Digital Hand-Held Oximeter (K991410) Ohmeda Biox 3760 Pulse Oximeter (K874104)

New Device Description:

Intended Use:

The BCI 3403 Sleep Screening Pulse Oximeter is a handheld, pulse oximeter that measures SpO_2, pulse rate, and pulse strength. It may be used as a spot check device in the hospital or clinical environments, including patient ground transport in clinical and EMS (Emergency Medical Services) settings. It additionally may be used to collect long term trend data in overnight sleep screening studies in the sleep lab or home. The BCI 3403 Sleep Screening Pulse Oximeter will provide reliable measurements on patients ranging from neonate to adults for spot checking applications and from pediatric to adult for sleep screening applications when using the appropriate BCI accessories.

Performance Data:

The design of this device utilizes currently available technology found in many legally marketed devices. The major difference between the new device and the predicate BCI 3401 Handheld Pulse Oximeter is the device software. Testing was done to ensure that the BCI

3403 Sleep Screening Pulse Oximeter would perform accurately within the environment(s) for which it is to be marketed.

Testing of device performance included: validation of the sleep screening summary statistics using prescribed inputs to the monitor from a simulator; comparative testing of the SpO_2 spot check and sleep screening perfomance against predicate devices; and overall software validation. The results demonstrated that the BCI 3403 Sleep Screening Pule Oximeter performs within its specifications.

Results of the testing described above indicate that there is no functional difference between the operation of the BCI 3403 Sleep Screening Pulse Oximeter and predicate devices. Based on these results, it is our determination that the device is safe, effective, and performs as well as the legally marketed predicate device(s).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully,

Donald Alexander
VP Regulatory Affairs

SIMS BCI, Inc.
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Waukesha, WI 53186-1856 U.S.A.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 4 2001

Mr. Donald J. Alexander
SIMS BCI, Inc.
N7 W22025 Johnson Road
Waukesha, WI 53186-1856

Re: K011156
BCI 3403 Sleep Screening Pulse Oximeter
Regulation Number: 870.2700
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: April 9, 2001
Received: April 16, 2001

Dear Mr. Alexander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if Known): K011156

Device Name: BCI 3403 Sleep Screening Pulse Oximeter

Indications For Use:

Intended Use:

The BCI 3403 Sleep Screening Pulse Oximeter is a handheld, pulse oximeter that measures SpO_2, pulse rate, and pulse strength. It may be used as a spot check device in the hospital or clinical environments, including patient ground transport in clinical and EMS (Emergency Medical Services) settings. It additionally may be used to collect long term trend data in overnight sleep screening studies in the sleep lab or home. The BCI 3403 Sleep Screening Pulse Oximeter will provide reliable measurements on patients ranging from neonate to adults for spot checking applications and from pediatric to adult for sleep screening applications when using the appropriate BCI accessories.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011156

Prescription Use ✓ OR Over-The_Counter Use _____
(Per 21 CFR 801.109)